

REMARKS

Claims 15-16, 22-26 and 30-39 are currently pending. Applicants respectfully submit the following remarks in response to the Office Action mailed February 7, 2006. Reconsideration and allowance of the claims is earnestly solicited.

Obviousness Rejections

Claim 15, and those depending from claim 15, were rejected as alleged obviousness under 35 USC 103(a) over Raymond '331 and Raymond '153 in view of Feler. Applicants respectfully traverse these rejections for the following reasons.

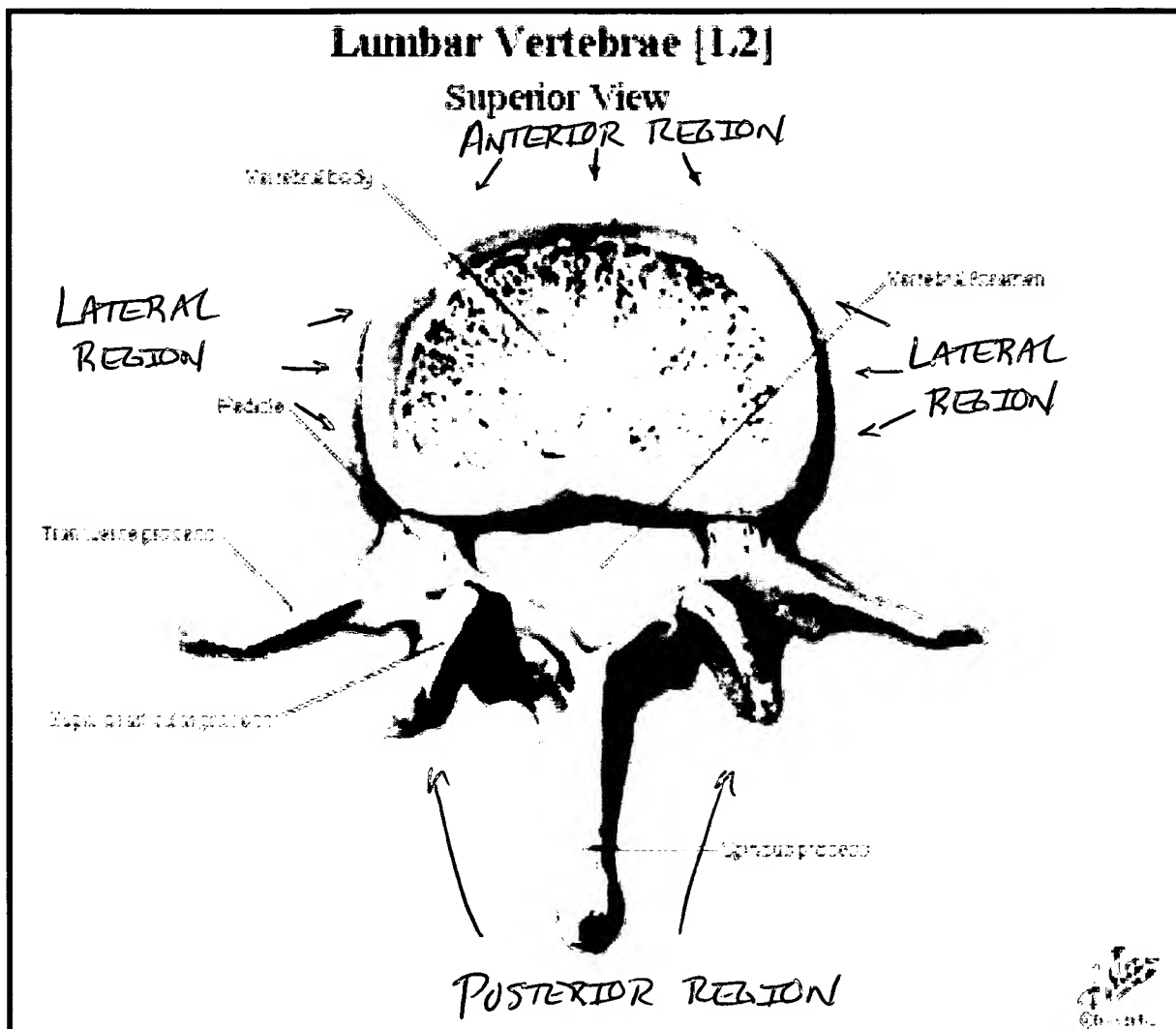
Claim 15, as amended, is directed at a method for assessing the proximity of a spinal nerve relative to a distal end of at least one probe or surgical tool being introduced towards a patient's spine, wherein the patient's spine is defined as having "a generally anterior region, a generally posterior region opposite from said generally anterior region, and generally lateral regions extending between said generally anterior region and said generally posterior region." With those limitations established in the preamble, the method includes a first step of "(a) emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced generally perpendicularly towards a generally lateral region of the patient's spine." The method then describes various additional steps, including: "(b) electromyographically monitoring muscles coupled to said spinal nerve to determine if a predetermined neuro-muscular response is elicited by the stimulus signal; (c) determining the relative distance between said spinal nerve and said distal end of said probe or surgical tool

based on the intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response; and (d) communicating to an operator said intensity level of said stimulus signal required to elicit said predetermined neuro-muscular response.”

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. In determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

In reviewing the Office Action, it appears that the Examiner has yet again mistaken the difference between a **spinal nerve** and an actual **spine**. The claimed invention, as clearly set forth in Claim 15, describes “emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced *generally perpendicularly towards a generally lateral region of the patient’s spine*.” The preamble of claim 15 clearly sets forth the basic physical regions of a patient’s spine: (1) a generally anterior region; (2) a generally posterior region opposite from the generally anterior region; and (3) generally lateral regions extending between the generally anterior region and the generally posterior region. With reference to the figure below, the generally Anterior Region is located at the top of the figure, and comprises the

region forming the front or anterior portion of the vertebral body. The Posterior Region is located at the bottom of the figure, and comprises the region rearward or behind the vertebral body (including the pedicle, transverse process, articular processes, and spinous process). The Lateral Regions extend between the Anterior Region and the Posterior Region on either side of the vertebral body.



With reference to FIGS. 1 and 4 in the subject application, it is clear that the approach of the present invention involves introducing a probe or surgical tool 20, 22 in a manner that is generally perpendicular to the lateral region of the patient's spine.

Neither of the Raymond references teaches, suggests or otherwise provides any motivation for the feature of "emitting a stimulus signal from an electrode disposed on a probe or surgical tool as said probe or tool is introduced *generally perpendicularly towards a generally lateral region of the patient's spine.*" Each Raymond reference merely illustrates advancing an electrified needle towards a nerve located in the arm of a patient, and neither makes any mention or teaching about spinal nerves, much less approaching the patient's spine in a manner that is generally perpendicular to a lateral region of the patient's spine.

The Examiner points to Feler to cure this defect, stating that "Feler is relied upon to teach that spinal nerves may be detected via a lateral approach." However, as explained before, Feler merely teaches positioning spinal chord leads via a **posterior** surgical approach. This is evident, among other places, with reference to FIG. 3 which clearly shows the stimulation lead 114 being applied to the posterior region (or – in normal parlance – the "back") of the patient's spine. Again, this is clear in that the patient facing **down** in FIG. 3. This is distinguishable from the lateral (or – in normal parlance- the "side") approach to the patient's spine, as set forth in Claim 15, which is clearly shown in FIG. 4 of the present application.

This is a significant distinction, in that the lateral approach to the spine presents a host of advantages over a posterior approach to the spine. These advantages include, but are not

necessarily limited to, the fact that a posterior approach necessarily requires that the surgeon pass the instruments closer to the spinal chord (which is housed within the vertebral foramen shown above) than with a lateral approach. This is because the lateral approach will cause the instruments to first contact the patient's spine at the lateral region of the vertebral bodies, which is located anterior to (or – in normal parlance – “in front of”) the vertebral foramen. This equates with reduced risk of impinging upon the spinal chord during a lateral approach procedure. In spinal procedures involving the placement of implants, the lateral approach is also advantageous in that the implants may be introduced directly into the intervertebral space between the lateral regions of adjacent vertebrae (via a generally lateral direction to the patient's spine), which does not require the removal of any of the posterior elements of the vertebrae (e.g. transverse process, spinous process, pedicle, etc...) as is oftentimes required during a posterior approach to the patient's spine.

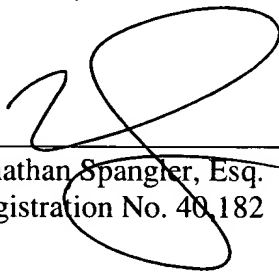
Based on the foregoing distinctions between Claim 15 and the prior art of record, Appellants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as now claimed) based on the cited references. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 16, 22-26 and 30-39, being dependant upon and further limiting independent claim 15, should be allowed for the reason set forth in support of the allowability of claim 15, as well as the additional limitations they contain.

Conclusion

Favorable consideration and allowance of the claims are respectfully requested. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

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